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| APPLICATION NO.         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/082,618              | 02/22/2002  | Alan D. Olstein      | 21001.005           | 4458             |
| 7590                    | 03/08/2005  |                      |                     |                  |
|                         |             |                      | EXAMINER            |                  |
|                         |             |                      | LUCAS, ZACHARIAH    |                  |
|                         |             | ART UNIT             | PAPER NUMBER        |                  |
|                         |             | 1648                 |                     |                  |
| DATE MAILED: 03/08/2005 |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b>             | <b>Applicant(s)</b>     |  |
|------------------------------|------------------------------------|-------------------------|--|
|                              | 10/082,618                         | OLSTEIN ET AL.          |  |
|                              | <b>Examiner</b><br>Zachariah Lucas | <b>Art Unit</b><br>1648 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 24 February 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-3 and 73-83 is/are pending in the application.  
4a) Of the above claim(s) 73-83 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-3 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

**DETAILED ACTION**

***Status of the claims***

1. Currently claims 1-3, and claims 73-83 are pending in the application. Claims 1-3 are under consideration in the application to the extent that they read on the elected invention, wherein the conjugate comprises the bacteriocin nisin.

In the prior action, mailed on July 28, 2004, claims 1-3, 8, and 65-67 were rejected. In the Response of February 24, 2005, the Applicant cancelled claims 8, and 65-67, and added new claims 78-83. In the Response, the Applicant noted that the Examiner had indicated in the prior action that claims 1-3 were allowable in the prior action.

While the claims were indicated as allowable on page 2 of the prior action, the claims were also claims 1-3 rejected on pages 10 (paragraph 18) and 11 (paragraph 20) of the action. The Office regrets the confusion and any inconvenience that this may have caused. Further, in view of the oversight, the present action is made Non-Final to afford the applicant the opportunity to respond the rejections.

2. Newly submitted claims 73-83 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are directed to methods for using the compositions of claims 1-3. The subject matter of these claims was previously restricted into separate groups (pending allowance of the composition claims) in the Requirement for Restriction mailed on May 5, 2003. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 73-83 withdrawn

from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **(Prior Rejection- Withdrawn)** Claims 66 and 67 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected as lacking sufficient written description support for the claims to the extent that they read on conjugates comprising fragments, homologs, and variants of bacteriocins and a transitional metal. In view of the cancellation of the rejected claims from the application, the rejection is withdrawn.

5. **(Prior Rejection- Withdrawn)** Claims 66 and 67 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for complexes comprising a bacteriocin and a transition metal, does not reasonably provide enablement for complexes comprising bacteriocin variants and transition metals. In view of the cancellation of the rejected claims from the application, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 66 and 67 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed invention wherein the peptide is the mature form of nisin, does not reasonably provide enablement for

embodiments wherein the peptide comprises the full length sequence of SEQ ID NO: 5 or of the sequence encoded by SEQ ID NO: 8 In view of the cancellation of the rejected claims from the application, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **(Prior Rejection- Maintained)** Claims 1-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over Siddigi et al. (U.S. Patent 5,541,113), in view of Olstein et al., (U.S. Patent 5,750,357), Meyer et al. (Arch Microbiol 167:67-77), and Friedman (J Agricult Food Chem 47(4): 1295-319), and of Pearce et al. (J Agric Food Chem 36: 7070-17).

In the prior action is was noted that the Applicant has amended the claims to require that the metal is cobalt, and by inserting the limitations of claim 6 into claim 1. The Applicant argued that this amendment avoided the prior art rejection. The argument was not found persuasive.

It was noted in the prior action that the Applicant had presented further arguments with respect to the teachings of Siddigi, Meyer, and Friedman in response to the rejection of the previous claims over the teachings of Siddigi in view of Olstein, Meyer, and Friedman, further in view of Buchman. In particular, the Applicant asserted that none of the references provide teachings regarding the binding of cobalt by nisin. Whereas the Friedman reference specifically provides teachings regarding the metal binding properties of lysinoalanine (LAL), the reference

does not refer to the metal binding properties of nisin, or the lanthionine amino acid structure contained by the peptide. The argument was found persuasive. However, the rejection was reformed so as to include the teachings of Pearce.

While the teachings of Friedman fail to suggest that nisin would have the same binding properties as the LAL containing peptides, such a suggestion is present in the teachings of Pearce. This reference indicates that lanthionine (LAN) has similar metal binding properties to LAL. See, abstract, pages 713. These teachings, particularly when seen in combination with the teachings of Friedman, which suggests that these cross-linked amino acids share certain properties), and with Surovoy (teaching the affinity for nisin and prenisin for zinc), and Weber (Int J Protein Res 3:225-59- teaching affinity between LAN and copper), would have suggested to those in the art that nisin, which comprising LAN, would also bind cobalt.

In view of the mistaken assertion on page 2 of the prior action that claims 1-3 were allowable, the Applicant did not respond to the rejection. The rejection, as reformed in the prior action, is therefore maintained.

9. **(Prior Rejection- Withdrawn)** Claims 66 and 67 were rejected under 35 U.S.C. 103(a) as being unpatentable over Siddigi in view of Olstein, Meyer, and Friedman, and further in view of Gasson. The Applicant argues that the rejection is overcome in view of the amendment of claim 1 such that it incorporates the limitations of claim 6. In view of the cancellation of these claims, the rejection is withdrawn.

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10. **(Prior Rejection- Maintained)** In the prior action, claims 1-3 were rejected as obvious over the teachings of Siddigi in view of Olstein, Meyer, Friedman, and of Pearce as described above, further in view of Buchman et al. (J Biol Chem 263(31): 16260-66). The rejection is therefore maintained.

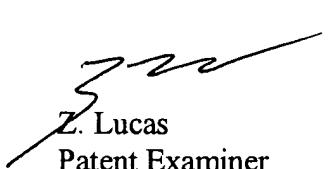
***Conclusion***

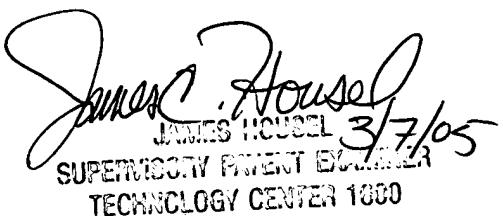
11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
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